Remarks

Upon entry of this Amendment, claims 20-25, 27-30, 32-39 and 42-54 will be pending. Applicants have amended claims 20, 25 and 43, currently on file, to more clearly define the scope of protection being sought. Support for the amendments can be found throughout the specification as filed, for example, at page 4, lines 18-23; page 5, lines 17-25; page 6, lines 1-4; page 8, lines 10-26; page 9, lines 8-17; page 11, lines 3-12; in the Examples and in claims 10 and 11, as originally filed.

Applicants have also added new claims 44 to 54 in order to claim additional embodiments of the invention. Support for the new claims can be found throughout the application as originally filed. Support for fusions of the antigen to the C-terminus of the coat protein, as recited in new claims 44 and 48, can be found, for example, at page 12, lines 21-24; page 14, lines 2-6, and in the Examples. Support for hepatitis C virus epitopes and *Salmonella typhi* epitopes, as recited in new claims 45 and 53, can be found, for example, in Examples III and IV. Support for a cytotoxic T-lymphocyte response, as recited in new claims 46 and 54, can be found, for example, at page 6, lines 1-4.

Applicants have additionally amended the specification at paragraph 0032 (page 7), paragraph 0047 (pages 10-11), paragraph 0063 (page 14), paragraph 0077 (pages 18-19) and at the title of Example IV (page 21).

35 U.S.C. 112, second paragraph

Applicants acknowledge with thanks the Examiner's withdrawal of the former rejection of claims 20-39 and 42 under 35 U.S.C. 112, second paragraph.

The Examiner has, however, further rejected claim 20, currently on file, under 35 U.S.C. 112 second paragraph, alleging the claim is indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention with respect to recitation of the phrase "derived." The Examiner alleged that the term

"derived" is not one which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification.

Without conceding to the correctness of the Examiner's rejection but in order to expedite prosecution of the instant application, Applicants have amended independent claim 20, replacing the phrase "a virus-like particle (VLP) derived from PapMV coat protein" with the phrase "a virus-like particle (VLP) comprising PapMV coat protein or modified PapMV coat protein, said PapMV coat protein or modified PapMV coat protein being capable of multimerization to form said VLP." Applicants assert that amended claim 20 submitted herewith complies with 35 U.S.C. 112, second paragraph, and, therefore, respectfully request the withdrawal of this rejection.

35 U.S.C. 112, first paragraph (Enablement)

Applicants acknowledge with thanks the Examiner's withdrawal of the former rejection of claims 20-31, 33-39 and 42 under 35 U.S.C. 112, first paragraph.

The Examiner has, however, further rejected claims 20-25, 27-30, 32-39, 42 and 43, under 35 U.S.C. 112, first paragraph, alleging the claims fail to comply with the enablement requirement. The Examiner alleged that the claims contain subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner stated claim 20, as currently amended, reads on any antigen, which when administered to an animal together with an effective amount of a PapMV adjuvant, has the ability to potentiate an immune response against the said antigen, wherein the immune response is humoral and/or cellular response. The Examiner alleged that the person of ordinary skill in the art would be unable to predict that any antigen fused to PapMV adjuvant would have the ability to potentiate a humoral and/or cellular immune response without first identifying the antigen as a B cell or a T cell epitope. In other words, the antigen that has not been identified as a B cell or a T cell epitope may not contribute to induction of humoral or cellular immune response, with or without

PapMV adjuvant. The Examiner also stated that it is known in the art that the induction of humoral or cellular immune response depends on the specificity of the antigenic epitope fused to the VLP, and not the VLP itself. The Examiner indicated that amending claim 20 to recite "A method of potentiating an immune response against a B cell or a T cell antigenic epitope in an animal (…)" would help overcome this rejection.

Applicants respectfully traverse the Examiner's rejection for the following reasons. An antigen, by definition, is a substance that evokes an immune response either alone or in combination with another molecule or substance, such as an adjuvant. As is known in the art and described in the instant specification (see, for example, page 11, lines 13-15, and page 12, lines 2-6), antigens may range in size from small molecules, such as haptens, up to very large molecules, such as proteins or parts of a virus. As such, an antigen may comprise a single epitope or it may comprise multiple epitopes, including combinations of B cell or T cell epitopes, and, therefore, may be capable of inducing more than one type of immune response. Identification of the exact nature of the epitope(s) comprised by the antigen, *i.e.* whether they are B cell or T cell epitopes or both, is not critical to the claimed method provided that the antigen is capable of inducing a humoral or cellular response, or both, when administered to an animal in combination with the recited PapMV adjuvant. In this regard, Applicants assert that the instant specification provides ample guidance with respect to how to make antigen/PapMV adjuvant combinations (see, for example, page 10, lines 1-15; page 11, lines 3-18; page 13, line 21 to page 14, line 21; and Examples I and III), how to administer the combination to an animal (see page 11, lines 19-25, page 12, lines 7-15; page 15, lines 5-11; and Example III), and how to test for and characterise an immune response against same (see, for example, page 5, lines 13 to page 6, line 4, and Examples I-III). Moreover, a wide variety of antigens, as well as a variety of methods of testing for and characterising immune responses, were well known in the art at the time of filing. Thus, Applicants submit that the teaching provided by the instant application, taken together with the knowledge in the art at the time of filing, would allow the skilled worker to select an appropriate antigen that, in combination with the PapMV adjuvant, produces a humoral and/or cellular immune response in an animal

and that the skilled worker could, therefore, readily make and use the invention as claimed.

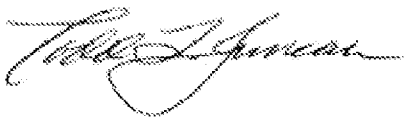
Solely for the purposes of expediting prosecution of the instant application, Applicants have, however, amended independent claim 20 to specify that the antigen "comprises one or more B-cell antigenic epitopes and/or one or more T-cell antigenic epitopes." Applicants submit that amended claim 20 submitted herewith complies with 35 U.S.C. 112, first paragraph, and, therefore, respectfully request that this rejection be withdrawn.

35 U.S.C. 112, first paragraph (Written Description)

Applicants acknowledge with thanks the Examiner's withdrawal of the former rejection of claims 20-31, 33-39 and 42 under 35 U.S.C. 112, first paragraph.

Conclusion

Applicants submit that all of the stated grounds for rejection have been properly traversed, accommodated or rendered moot. Applicants, therefore, respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favourable consideration of this Amendment and Reply is respectfully requested.



Todd L. Juneau, Reg. No. 40,669
JUNEAU PARTNERS, PLLC
(703) 706-0405